DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 12, 2015

C.R. Bard, Inc.
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K143522
Trade/Device Name: Presto Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: MAV
Dated: December 26, 2014
Received: December 29, 2014

Dear Mr. Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143522

Device Name
Presto™ Inflation Device

Indications for Use *(Describe)*
The Presto™ Inflation Device is indicated for use with angioplasty balloon dilatation catheters to create and monitor the pressure in the angioplasty balloon dilatation catheter and to deflate the angioplasty balloon dilatation catheter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Presto™ Inflation Device

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2939

Fax: 480-449-2542

Contact: Timothy Wade, Regulatory Affairs Specialist

Date November 21, 2014

Subject Device Name:

Device Trade Name:	**Presto™ Inflation Device**
Common or Usual Name:	Balloon Inflation Syringe (21 CFR 870.1650; Product Code: MAV)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Device:

- SCIMED Encore Inflation Devices (K955869; cleared March 22, 1996)

Device Description:

The Presto™ Inflation Device is an ultra high pressure, large volume inflation device used to inflate, monitor pressure, and deflate angioplasty balloon dilatation catheters. It is a one-piece, 30 mL disposable inflation device rated for 40 atm with a lever-lock design that controls the piston, a manometer, and a high-pressure connecting tube with a male Luer rotating adapter. Also enclosed is a high-pressure 3-way stopcock to aid in preparation and use of the device. The manometer measures pressures ranging from 0 atm up to 40 atm in 1 atm increments. The accuracy of the manometer has been determined to be within ±1.6 ATM. These products are not made with natural rubber latex.

Indications for Use of Device:

The Presto™ Inflation Device is indicated for use with angioplasty balloon dilatation catheters to create and monitor the pressure in the angioplasty balloon dilatation catheter and to deflate the angioplasty balloon dilatation catheter.

Comparison of Indications for Use to Predicate Devices:

The indications for use statement for the Presto™ Inflation Device is similar to the predicate device, with the addition of angioplasty for clarification purposes, and does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process. Therefore, the subject device, the Presto™ Inflation Device, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The Presto™ Inflation Device has the following similarities to the predicate device:

- Same intended use
- Similar indications for use
- Same target population
- Same operating principle
- Similar materials
- Same fundamental scientific technology

- Similar packaging materials and configurations
- Same method of sterilization

The differences between the predicate and subject device include differences in syringe volume, rated inflation pressure, pressure reading accuracy, material composition of components, and changes in packaging configuration.

Performance Data:

To demonstrate substantial equivalence of the subject device, the Presto™ Inflation Device to the predicate device, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents and recognized standards on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Syringe Volume
- Rated Inflation Pressure
- Fatigue Testing
- ISO Luer and Stop Cock Hub Testing
- Pressure Reading
- Tubing Tensile Strength
- User Validation (Bubble Visualization)
- Syringe Barrel Graduation Markings
- Packaging
    - Visual Inspection
    - Dye Penetration
    - Tray Seal Tensile

Product will have a viable shelf life based upon successful completion of testing performed in accordance with ASTM F1980-07, “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”, FDA Guidance, “Shelf Life of Medical Devices”, issued April 1991 and the Bard internal stability program. Additionally, biocompatibility tests were performed in accordance with ISO 10993-1: 2009, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process”. The Presto™ Inflation Device, when connected to an angioplasty balloon dilatation catheter, is a closed

system and does not deliver contrast/saline to the circulatory system. Successful testing for Cytotoxicity, Sensitization and Intracutaneous Reactivity show the devices are biocompatible for their intended use. Additionally, pyrogenicity testing is conducted to support labeling claims.

The results from these tests demonstrate that the technological characteristics and performance criteria of the Presto™ Inflation Device is comparable to the predicate devices and that it can perform in a manner equivalent to balloon inflation devices currently on the market with the same intended use.

Conclusions:

The subject device, the Presto™ Inflation Device, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Presto™ Inflation Device is substantially equivalent to the legally marketed predicate device.